U.S. Department of Justice

United States Attorney
Southern District of New York

86 Chambers Street
New York, New York 10007

March 17, 2015

BY ECF

Honorable Colleen McMahon
United States District Judge
United States Courthouse, 500 Pearl Street
New York, NY 10007

Re: *United States* et al. ex rel. *Kester v. Novartis Pharmaceuticals, Corp.*, et al., 11 Civ. 8196 (CM) (JCF)

Dear Judge McMahon:

On behalf of the United States (the "Government"), the States of California, Georgia, Indiana, Illinois, Maryland, Michigan, New Jersey, New York, Oklahoma, Washington, and Wisconsin (the "Litigating States"), and the *qui tam* relator David Kester ("Relator"), we write respectfully to update the Court regarding an urgent development in this case. On February 17, Novartis announced it was waiving attorney-client privilege to assert a defense of good faith reliance on legal advice. It also indicated the volume of the waiver documents would *not* "be significant." But, on March 13, with barely a month left in fact discovery, Novartis produced over 500,000 pages of documents that it had previously withheld or redacted – including over 331,000 pages of documents that Novartis previously had withheld in full. Novartis's belated waiver has caused postponements of previously scheduled depositions and also added many names to the list of the witnesses that plaintiffs need to depose. Its last-minute production of more than half a million pages of purportedly relevant and privileged documents has blindsided plaintiffs and is making it impossible for us to litigate this case under the current schedule.

In light of these developments, we respectfully request a two-month extension of the discovery deadlines and a corresponding adjournment of the trial-ready date or, in the alternative, for an order precluding Novartis from advancing an advice-of-counsel or good faith defense at trial. We have sought defendants' consent. Novartis indicated it objects to our requests for a two-month extension of the discovery deadlines and a corresponding adjournment of the trial-ready date, while co-defendant Accredo indicated it does not object to our requests.

Novartis's Belated Decision to Waive Privilege and Its Initial "Waiver" Production

On February 17, *i.e.*, less than 60 days before the close of fact discovery, Novartis announced that it had decided to waive privilege and to assert an advice-of-counsel defense based on, *inter alia*, testimony from two lawyers. That announcement came nearly seven months after Novartis indicated it did *not* intend to assert an advice-of-counsel defense, in response to a July 2014 inquiry from the Government on that subject.

Immediately after learning of that waiver decision, plaintiffs asked Novartis to produce all documents that could no longer be withheld under a claim of privilege. Novartis indicated that did "not anticipate that the volume of these documents will be significant." In that vein, Novartis made an initial production of 126 new documents on February 28, along with a few

hundred un-redacted documents that it previously had redacted for privilege. In the meantime, plaintiffs adjourned the depositions of numerous Novartis witnesses because, without the documents to be produced under the waiver, we could not effectively depose those witnesses.

Plaintiffs requested Novartis to complete its production of the previously withheld and redacted documents by March 4. When Novartis refused, plaintiffs moved to compel. In response, Novartis advised Magistrate Judge Francis on March 2 that it would make "a rolling production," but refused to commit to a firm deadline for completing its production. Novartis also did not indicate to either plaintiffs or Judge Francis that the volume of documents it would produce was not just "significant," but in fact numbered in the hundreds thousands of pages (*i.e.*, more than 1,000 times larger than the initial production of 126 documents made on February 28).

During a March 4th discovery conference, Judge Francis ordered Novartis to complete production by Friday, March 13, and noted that he was free to review documents in camera before then. Judge Francis also determined that depositions related to Exjade should be postponed until Novartis finished producing these documents. After securing the extension it requested from Judge Francis, Novartis refused to either make additional productions on a rolling basis or participate in meet-and-confer regarding specific documents it continued to withhold under a claim of privilege. Yet, while plaintiffs were waiting for Novartis's production of the privilege waiver documents to prepare for depositions, Novartis counsel were working actively to subpoena and schedule depositions of third-party witnesses.

On March 13, Novartis Produced More Than 500,000 Pages of Previously Withheld or Redacted Documents

Late on Friday, March 13, Novartis made a massive production of documents that contained more than 500,000 pages in more than 27,000 distinct documents. This included more than 331,000 pages of documents that Novartis had withheld in the entirety under a claim of privilege,[1] as well as approximately 170,000 pages previously produced with redactions. The newly produced documents also lacked metadata identifying each document's "custodian," making it impossible to determine fully the sources of the documents.

Due to the size of the March 13th production, plaintiffs are just beginning to analyze these documents. Based on a preliminary review of the 311 documents that Novartis identified as containing legal advice it intends to rely upon, it appears that, unlike in a typical case involving the advice-of-counsel defense, Novartis is not relying on a memorandum or report that summarizes the information supplied to counsel and sets forth counsel's legal advice. Thus, to piece together the basic elements of Novartis's advice-of-counsel defense (*e.g.*, what advice it sought, what information it provided to counsel, what advice counsel gave, and whether Novartis duly followed such advice), plaintiffs will be required to go through witnesses' handwritten notes, draft power-points, and e-mails and depose numerous witnesses.

Further, it is apparent from even a cursory review of the March 13th production that Novartis's "waiver" is unfairly narrow and selective. For instance, just the 311 documents on which Novartis intends to rely contain 140 privilege redactions. To take just one example, the

[1] Exact document and page counts are impossible, because one CD, which Novartis produced labeled as "Additional Kaye Scholer Documents," contains approximately 628 natively produced emails that have not yet been BATES stamped.

handwritten notes of Novartis's in-house lawyer, Steven Goldfarb, in which he wrote down the legal advice given to him by outside counsel Joseph Metro, contain numerous large "redacted" segments which Novartis has logged as being privileged because these notes "reflect[] legal advice regarding EPASS patient administration." At this juncture, this and other improper redactions serve no purpose other than delay — while plaintiffs intend to challenge the improper redactions, doing so will take time and could result in further postponement of depositions of the Novartis witnesses.[2]

Extending the Discovery Deadlines Is Warranted

Given these circumstances, we respectfully submit that a two-month extension of the fact and expert discovery deadlines is appropriate. To date, the Government, the Litigating States, and the Relator have worked assiduously to move the case forward. As summarized above, to expedite Novartis's production of the privilege waiver documents, plaintiffs sought and obtained an order from Judge Francis imposing a firm deadline for completion of such production. Further, while waiting for Novartis to complete its production, plaintiffs have proceeded with depositions of Novartis employees who did not appear to be involved with seeking or implementing legal advice. We also coordinated with Novartis to schedule depositions of third-party witnesses at the Exjade pharmacies Accredo and Bioscrip. However, due to Novartis's 11th-hour decision to waive privilege, we had to postpone depositions of numerous Novartis employees because, without the waiver documents, it was impossible to know whether they took part in seeking legal advice, providing facts to counsel, or implementing legal advice.

What we did not expect – especially in light of Novartis's prior representation that it did "not anticipate the volume of [the privilege waiver] documents will be significant" – is the sheer volume of the documents that Novartis produced on March 13. Novartis has been in possession of these documents for years, and even if its decision to waive privilege was recent, it knew the approximate volume and should have been upfront about this with plaintiffs and the Court. Instead, Novartis chose to produce, at the last minute, more than half a million pages of documents it has concluded to be both relevant and privileged. This is inappropriate and unfair — it prevents plaintiffs from reviewing them and utilizing them in depositions and significantly compromises our ability to prepare for trial.

Novartis had made clear it intends to rely on the advice-of-counsel defense "to emphasize that plaintiffs cannot prove the requisite intent to violate the AKS." To refute that defense, plaintiffs need additional time to go through the tens of thousands of privilege waiver documents in Novartis's March 13th production — both to determine how they affect the depositions of the Novartis witnesses we have already noticed and to identify the additional witnesses who will need to be deposed.[3] Accordingly, we ask that the Court (*i*) extend the deadline for completing

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[2] Novartis also is trying to selectively limit the scope of its waiver. As set forth in the Government's request pending before Judge Francis, Novartis is simultaneously asserting a "good faith defense" and refusing to permit discovery into legal review that, according to its own employees' sworn testimony, underpins that defense. [Dkt. 372]

[3] To give just one example — the March 13th production shows that Novartis intends to rely on legal advice it received from two lawyers from the ReedSmith law firm, Christine Bloomquist and Joseph Metro. Yet, Novartis has *never* identified Ms. Bloomquist as either a potential witness or a custodian in any of its disclosures or prior communications.

fact discovery from April 17 to June 15, 2015; (*ii*) extend the deadline for completing expert discovery from May 29 to August 4, 2015; and (*iii*) adjourn the trial-ready date from June 26 to September 9, 2015. In the alternative, we ask that the Court preclude Novartis from asserting an advice-of-counsel or a good faith defense at trial.

We thank the Court for its consideration of this letter and these requests.

Respectfully,

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